K013781

FEB 0 6 2002

ATTACHMENT H

SUMMARY OF SAFETY & EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Mitek Products is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Mitek Products choose to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

The summary regarding the adverse health effects of the proposed RigidFix™ 2.7mm BTB Cross Pin Kit is as follows:

Trade Name: RigidFix™ 2.7mm BTB Cross Pin Kit

Sponsor: Mitek Products
249 Vanderbilt Avenue
Norwood, MA 02062
Registration: 1221934

Device Generic Name: Appliance for reconstruction of bone to soft tissue

Classification: According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Devices: Mitek - RigidFix™ 2.7mm BTB Cross Pin Kit (K974291)
Linvatec BioScrew® Absorbable Interference Screw (K973758)

All of the devices mentioned above have been determined substantially equivalent by FDA.

Device Description: The device described in this 510(k) is a sterile, disposable, device designed for single patient use only. The cross pins are constructed of bioabsorbable Poly Lactic Acid (PLA).

Indications for Use: The RigidFix™ 2.7mm BTB Cross Pin Kit is indicated for femoral and tibial fixation of autograft or allograft ACL bone-tendon-bone (BTB) grafts.

Safety and Performance: Functional and integrity bench testing and Biocompatibility testing (according to the FDA guidance document, ODE Blue Book Memoradum #G95-1, 1995, Use of International Standard ISO-10933, "*Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*" were performed, and the data supported the substantial equivalence of the proposed RigidFix™ 2.7mm BTB Cross Pin Kit. Specifically, testing was performed to determine the initial fixation strength of the proposed RigidFix™ 2.7mm BTB Cross Pin Kit when used for Bone-Tendon-Bone grafted ACL Reconstructions.

Conclusion: Based on the Indications for Use, design, technological characteristics and safety and performance testing, the proposed RigidFix™ 2.7mm BTB Cross Pin Kit has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 6 2002

Ms. Jennifer Johnson
Regulatory Affairs Associate
Mitek Products
Ethicon, Inc., a Johnson & Johnson Company
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K013781
Trade Name: Rigidfix ™ 2.7mm BTB Cross Pin Kit
Regulation Number: 888.3030
Regulatory Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HTY, MAI
Dated: November 13, 2001
Received: November 14, 2001

Dear Ms. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FEB 0 6 2002

510(k) Number (if known): 013781

Device Name: Rigidfix(tm) 2.7mm BTB Cross Pin Kit

Indications for Use: The Mitek RigidFix 2.7mm BTB Cross Pin Kit is indicated for femoral and tibial fixation of autograft or allograft ACL bone-tendon-bone grafts.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

Mark N Milken

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013781